UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

JAZZ PHARMACEUTICALS, INC. and JAZZ PHARMACEUTICALS IRELAND LIMITED, Plaintiffs, v. AMNEAL PHARMACEUTICALS LLC, et al., Defendants.	Civil Action No. 13-391 (ES)(JAD) (consolidated) ***Document Electronically Filed***

DEFENDANTS' RESPONSIVE *MARKMAN* BRIEF

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Defendants Amneal Pharmaceuticals, LLC ("Amneal"); Lupin Limited, Lupin Pharmaceuticals, Inc. and Lupin Inc. (collectively, "Lupin"); and Watson Laboratories, Inc. ("Watson") (collectively, Amneal, Lupin and Watson are referred to herein as "Defendants") respectfully submit this brief in response to Plaintiffs Jazz Pharmaceuticals, Inc.'s and Jazz Pharmaceuticals Ireland Ltd.'s (collectively, "Jazz") Opening *Markman* Brief (D.I. 323, "Jazz Br.").

ARGUMENT

I. The '203 Patent.

A. "The components are admixed sequentially" / "the components are admixed simultaneously."

1. The terms "the components are admixed sequentially" and "the components are admixed simultaneously" are indefinite.

Jazz alleges the terms "the components are admixed sequentially" and "the components are admixed simultaneously" as they appear in claims 7 and 8, respectively, of the '203 patent require no construction, because the "meaning is readily apparent to a person of ordinary skill in the art." (Jazz Br. at 1; *see also id.* at 11.) Jazz's position does not address the obvious ambiguity created by the claims. Indeed, Jazz fails to provide any explanation, or point to any support (intrinsic ***or*** extrinsic), that informs the skilled artisan how to identify what is meant by components that are admixed sequentially or simultaneously with reasonable certainty.

First, Jazz does not address that the disputed term "components" is not defined in the specification and has no antecedent basis in independent claim 1 (upon which claims 7 and 8 depend). Jazz states, without providing any support, that "[b]ased upon the disclosures of the '203 patent, a skilled artisan would understand with reasonable certainty what the components

are that are being admixed."[1] (Jazz Br. at 12.) Jazz takes the position that a person of ordinary skill in the art would readily understand the components of claim 1 to be "a salt of GHB, an aqueous medium and a pH adjusting agent." (*Id.*) But claim 1 does not recite or otherwise require a pH adjusting agent as Jazz suggests; rather, at most, the specification states that a pH adjusting agent is ***preferable*** in certain embodiments. (*See* White Decl. Ex. 1[2], the '203 patent at col. 6, ll. 37–39 ("In certain other embodiments of the present invention, the pharmaceutical composition may comprise a pH adjusting or buffering agent.") (LUP.GHB 007054); *id.* at col. 12, ll. 39–40 ("In certain embodiments of the invention, a pH-adjusting agent may be added to the composition.") (LUP.GHB 007057); *id.* at col. 19, ll. 18-20 ("***Preferably***, the aqueous medium will contain a pH-adjusting or buffering agent." (emphasis added)) (LUP.GHB 007061); *id.* at col. 70, ll. 2-10 (LUP.GHB 007086).)

The Federal Circuit has long held that statements of preference in the specification do not limit claim scope. *See Abbott Labs. v. Baxter Pharm. Prods., Inc.*, 334 F.3d 1274, 1279–80 (Fed. Cir. 2003); *Cadence Pharm. Inc. v. Exela PharmSci Inc.*, 780 F.3d 1364, 1373 (Fed. Cir. 2015); *King Pharm., Inc. v. Eon Labs, Inc.*, 616 F.3d 1267, 1275 (Fed. Cir. 2010); *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1288 (Fed. Cir. 2009); *Phillips v. AWH Corp.*, 415 F.3d 1303, 1323 (Fed. Cir. 2005) ("[A]lthough the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments."); *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) (noting that it is

[1] Jazz fails to provide its position on the education and experience of a person of ordinary skill in the art as relevant to the '203 patent, and yet appears to rely on the same unidentified skilled person in construing the claims. *Nazomi Commc'n, Inc. v. Arm Holdings, PLC*, 403 F.3d 1364, 1370–71 (Fed. Cir. 2005) (establishing importance of identifying skill level in construing claims). Therefore, Jazz's statements regarding any alleged understanding of a person of ordinary skill in the art are wholly unsupported.

[2] References to "White Decl." are to the Declaration of Natasha L. White (and exhibits thereto) in Support of Defendants' Opening *Markman* Brief (D.I. 322).

inappropriate to import limitations from the specification to limit facially broad claims "unless the patentee has demonstrated a clear intention to limit the claim scope using 'words or expressions of manifest exclusion or restriction.'" (citations omitted)). And as the '203 patent specification states, it is possible to obtain the claimed pH range without the addition of a pH adjusting agent. (*See* White Decl. Ex. 1, the '203 patent at col. 38, ll. 31–34 (referring to "pH unadjusted solutions and within the pH range desired for this formulation (pH 6.0-8.0)") (LUP.GHB 007070).) In sum, because a pH adjusting agent is neither explicitly nor implicitly required by claim 1, Jazz's argument that "components" means "a salt of GHB, an aqueous medium and a pH adjusting agent" falls flat.

Compounding the ambiguities here, without a pH adjusting agent, claim 1 would only arguably identify two ingredients to be admixed—GHB salt and an aqueous medium, which cannot be done sequentially (as required by claim 7) since there would be no sequence, only a single event– ingredient A added to ingredient B and mixed. (*See also* D.I. 321, "Defs. Br.", at 9–10.)

Furthermore, the specification does not limit the term "components" as Jazz suggests but instead explicitly allows "components" to include additional possibilities, such as flavoring agents or excipients. (*See, e.g.*, White Decl. Ex. 1, the '203 patent at col. 8, ll. 56–57 ("Other components, such as flavoring agents, salts, and the like, may be added to the composition.") (LUP.GHB 007055); *id.* at col. 9, ll. 63–66 ("The components of the GHB composition of the present invention, GHB, an aqueous medium, pH adjusting or buffering agent, excipients, preservatives, flavoring agents, and/or other components . . .") (LUP.GHB 007056).) Yet, without a clear definition, or an antecedent basis as discussed above, a person of ordinary skill in

the art cannot discern what (if any) additional components are to admixed sequentially or simultaneously, as required by the claims. (Defs. Br. at 6–7.)

In sum, Jazz's argument pretends the meaning of "components" is clear, but in doing so ignores the bulk of the specification. In other words, Jazz fails to read the claims in the context of the entirety of the intrinsic record as required. *Medrad, Inc. v. MRI Devices Corp*., 401 F.3d 1313, 1319 (Fed. Cir. 2005) ("We cannot look at the ordinary meaning of the term . . . in a vacuum. Rather, we must look at the ordinary meaning in the context of the written description and the prosecution history."); *Nystrom v. TREX Co*., 424 F.3d 1136, 1144-45 (Fed. Cir. 2005) (a party "is not entitled to a claim construction divorced from the context of the written description and prosecution history").

For at least these reasons, the terms "the components are admixed sequentially" and "the components are admixed simultaneously" in the '203 patent are indefinite for failing to "inform those skilled in the art about the scope of the invention with reasonable certainty." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2129 (2014).

2. To the extent not indefinite, the terms "the components are admixed sequentially" and "the components are admixed simultaneously" must be construed consistent with their plain and ordinary meaning.

To the extent the terms "the components are admixed sequentially" and "the components are admixed simultaneously" are not indefinite, they must be construed consistent with the plain and ordinary meaning. Jazz argues that Defendants' proposed construction "inject[s]" a separate "'adding' step" into its construction of admixing. (Jazz Br. at 11.) Defendants' construction does no such thing; it distinguishes admixing from adding, consistent with the specification. (*See* Ex. 1 White Decl., the '203 patent at col. 4, l1. 15-17 ("These pH values will produce compositions resistant to microbial growth in an aqueous medium if the amount of GHB ***added, admixed, or dissolved*** . . . .") (emphasis added) (LUP.GHB 007053).) In fact, Jazz implicitly concedes that

admixing must be distinct from adding, as it cites that same passage from the specification that uses the disjunctive "or" when listing "admixed" and "added." (Jazz Br. at 11.)

Despite Jazz's recognition that adding and admixing must have different meanings, Jazz fails to address what the plain and ordinary meaning of admixed is, including in light of the specification. Defendants on the other hand, as explained in their Opening Brief, looked to the '203 patent specification which establishes that alleged components are not admixed until they have been (1) combined, *i.e.*, added together; and (2) mixed. (Defs. Br. at 7–8.) Extrinsic evidence also supports Defendants' construction. (*Id.* at 8.)

With respect to "sequentially" and "simultaneously," Jazz complains that there is no support for Defendants' construction in the '203 patent. (Jazz Br. at 11.) Jazz's argument misses the mark. The '203 specification provides no guidance as to what is meant by "sequentially" or "simultaneously" admixing; and therefore, a person of ordinary skill in the art would have turned to available extrinsic evidence to understand the plain and ordinary meaning of the terms. (Defs. Br. at 11–12); *see also Janssen L.P. v. Barr Labs, Inc.*, 2009 WL 424389 at *4 (D.N.J. 2009). The plain and ordinary meaning of "simultaneous" is "existing or occurring at the same time" and the plain and ordinary meaning of "sequential" is "following in sequence." (White Decl. Ex. 2, NINTH NEW COLLEGIATE DICTIONARY – MERRIAM WEBSTER 1074, 1099 (1988) (LUP.GHB. 003671-72).)

Jazz does not dispute that Defendants' constructions reflect the plain and ordinary meaning of the terms, as a person of ordinary skill in the art would understand them; in fact, Jazz's own examples of what it considers would be sequential or simultaneous admixing are consistent with Defendants' constructions. (*See* Jazz Br. at 12.) For example, Jazz states "[s]imultaneous admixing of the components, on the other hand, would require admixing GHB,

an aqueous medium, and a pH-adjusting agent all ***at the same time***." (*Id*. (emphasis added).) Which is exactly what Defendants' proposed: "the act of creating a mixture by adding components ***at the same time***." (Defs. Br. at 5.)

Thus, to the extent the terms "the components are admixed sequentially" and "the components are admixed simultaneously" are not indefinite, Defendants' construction should be adopted as it is consistent with the plain and ordinary meaning of the terms.

II. The '650 and '619 Patents.

A. "Third container means."

Despite Jazz's best efforts to muddy the waters and avoid the controlling law (Jazz Br. at 5–9), the term "third container means" is a quintessential means-plus-function element defined by three claimed functions, yet lacks any clearly-linked precise structure in the specification to perform those functions, as demonstrated in Defendants' opening brief. (Defs. Br. at 12–19.) Thus, this term and the claims in which it appears—claims 17 and 18 of the '650 patent, and claims 16 and 17 of the '619 patent—should be held indefinite under well-established claim construction law. (*Id.*)

As a threshold matter, the Court should decline Jazz's invitation to postpone an indefiniteness ruling on this term. (*See* Jazz Br. at 8.) As Chief Judge Simandle noted after the Supreme Court's decision in *Nautilus*, "indefiniteness is a significant issue to be adjudicated at claim construction . . . ." *Mycone Dental Supply Co., Inc. v. Creative Nail Design, Inc.*, No. 11-4380, 2014 WL 3362364, at *4 (D.N.J. July 9, 2014); s*ee also Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1368–74 (Fed. Cir. 2014) (affirming the district court's indefiniteness ruling at claim construction post-*Nautilus*). In fact, the Federal Circuit has routinely affirmed means-plus-function indefiniteness rulings at claim construction—the type of indefiniteness at issue here—both pre- and post-*Nautilus*. *E.g., Cardiac Pacemakers, Inc. v. St. Jude Med. Inc.*, 296

F.3d 1106, 1107–12 (Fed. Cir. 2002); *Noah Sys., Inc. v. Intuit Inc.*, 675 F.3d 1302, 1305–09 (Fed. Cir. 2012); *Media Rights Techs., Inc. v. Capital One Fin. Corp.*, 800 F.3d 1366, 1368–70 (Fed. Cir. 2015). What is more, the parties' opening briefs show that the indefiniteness dispute in this case can be determined based on the intrinsic evidence alone. The record is therefore complete, and deferring this issue to summary judgment or trial would merely permit unnecessary additional litigation of indefinite patent claims.

Jazz's request for delay is perhaps unsurprising, because its substantive arguments are plainly and legally insufficient to avoid indefiniteness. Jazz first tries to argue that "third container means" is somehow not subject to means-plus-function law, despite the claim language confirming the legal presumption that it is. (Jazz Br. at 6–8.) Then, against the controlling law, Jazz attempts to muster a corresponding precise structure in the specification for the claimed "third container means"—despite not having offered any such structure in its proposed construction. (*Id.* at 8–9.) As shown below, these arguments are meritless.

1. Under the controlling law, Jazz is incorrect that the "third container means" does not trigger means-plus-function claim construction requirements.

If Jazz had its way, claim construction of this term would have nothing to do with the Federal Circuit's means-plus-function law under § 112, ¶ 6. (*See* Jazz Br. at 6.) Jazz would simply rewrite the claim term "third container means" as "third container," and then generically construe it as such. (*See id.*) Yet Jazz identifies nothing in the claims or the specification to justify this extraordinary departure from fundamental claim construction law. (*See id.* (citing '650 patent at claim 17, col. 15 l. 62 – col. 16 l. 37).)

Jazz further argues that its proposed construction is correct because another defendant in a separate case ultimately decided not to litigate this term and instead agreed to Jazz's construction—but that is of course legally irrelevant to the claim construction dispute in this

case. (*See* Jazz Br. at 7.) Roxane's decision to streamline the numerous issues in its own litigation, rather than having the Court adjudicate indefiniteness of the "third container means," plainly cannot be deemed probative claim construction evidence here.[3] Likewise, Defendants' agreement to constructions of "second" and "first" container means in this case is irrelevant to this dispute. (*See* Jazz Br. at 8.) Jazz's reliance on Defendants' willingness to narrow the terms for construction, rather than litigate every term in every claim, is inappropriate and should be rejected. (*See id.*)

When Jazz does acknowledge the governing means-plus-function law, Jazz incorrectly asserts that the claim term "third container means" is not subject to that law—largely through a misapplication of the Federal Circuit's precedent. (Jazz Br. at 7–8.) First, to the extent Jazz implies that the phrase "means for" invokes § 112, ¶ 6, but that the word "means" alone does not, Jazz is utterly mistaken. (*See id.*) The Federal Circuit has repeatedly ruled that the use of the word "means" triggers a legal presumption that the requirements of § 112, ¶ 6 apply. *E.g.*, *Biomedino, LLC v. Waters Techs. Corp.*, 490 F.3d 946, 950 (Fed. Cir. 2007); *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1349 (Fed. Cir. 2015). Second, Jazz's suggestion that the claims here do not follow the term "third container means" with a "recitation of the function performed"—another hallmark of means-plus-function claiming—is also false. (Jazz Br. at 7–8.) In fact, the claims explicitly recite no less than three functions for this claim element.[4] ('650 patent at claim 17; '619 patent at claim 16.)

[3] Underscoring its irrelevance, this third-party agreed construction falls short of being a prior adjudicated district court construction, which itself may not even be entitled to deference in these circumstances. *See Ravo v. Tyco Healthcare Grp. LP*, No. 11–CV–01637, 2013 WL 3326657, at *6 (W.D. Penn. Mar. 13, 2013) (prior district court claim construction decisions given deference "unless there is . . . a new party that raises new arguments").

[4] The use of the word "means" here in addition to the recitation of function also undermines Jazz's reliance on *Greenberg v. Ethicon Endo-Surgery, Inc.*, 91 F.3d 1580, 1583 (Fed. Cir.

In another effort to avoid the requirements of § 112, ¶ 6, Jazz simply declares that the word "container," modifying "means," imputes sufficient structure to rebut the legal presumption of means-plus-function claiming here, against the law and intrinsic evidence. (Jazz Br. at 8.) But as the Federal Circuit instructed in *TriMed, Inc. v. Stryker Corp.*, a case on which Jazz itself relies (Jazz Br. at 8), "[s]ufficient structure exists when the claim language specifies *the exact structure that performs the functions in question* without need to resort to other portions of the specification or extrinsic evidence for an adequate understanding of the structure." 514 F.3d 1256, 1259–60 (Fed. Cir. 2008) (emphasis added).

Here the word "container" alone could not possibly specify such "exact structure," particularly when that *same* modifier is used for the distinct "first" and "second" means as well. (White Decl. Ex. 6, '650 patent at claim 17; White Decl. Ex. 7, '619 patent at claim 16.) Thus, the exact structure of the "third container means" could only be disclosed by clearly linked portions of the specification. This absence of detailed and specific structure in the claim also distinguishes "third container means" from the other two cases on which Jazz relies. (Jazz Br. at 8.) *See Cole v. Kimberly-Clark Corp.*, 102 F.3d 524, 531 (Fed. Cir. 1996) ("The claim describes not only the structure that supports the tearing function [(*i.e.* perforations)], but also its location (extending from the leg band to the waist band) and extent (extending through the outer impermeable layer)."); *Envirco Corp. v. Clestra Cleanroom, Inc.*, 209 F.3d 1360 (Fed. Cir. 2000) ("Likewise, in this case the claims recite sufficient structure (*i.e.* a baffle disposed radially outward from the centrifugal fan, with inner surfaces for directing airflow)."). Jazz's attempts to evade means-plus-function claim construction requirements for this term should be rejected.

1996). (*See* Jazz Br. at 8.) There the disputed claim term did not recite "means" at all and was governed by the *opposite* presumption that means-plus-function requirements did *not* apply. *Greenberg*, 91 F.3d at 1584.

2. Jazz fails to point to any corresponding "third container means" structure in the specification to avoid indefiniteness as a matter of law.

As expected, Jazz does not identify any structure in the specification that is explicitly linked to the "third container means." (Jazz Br. at 9.) None of Jazz's specification excerpts even mention this element, much less clearly link any structure to all three of its claimed functions. (*Id.*; *see* Defs. Br. at 16–18.) Instead, Jazz insists that there are "implicit" disclosures "to an ordinarily skilled artisan" of what structures "can" be used. (Jazz Br. at 9.) But Jazz's argument ignores the bounds of means-plus-function claiming: "That ordinarily skilled artisans could carry out the recited function in a variety of ways is precisely why claims written in 'means-plus-function' form must disclose the particular structure that is used to perform the recited function." *Blackboard, Inc. v. Desire2Learn Inc.*, 574 F.3d 1371, 1385 (Fed. Cir. 2009).

Jazz first relies on specification disclosures of "container means" generally, but the only alleged "structure" those disclosures provide (and Jazz highlights) are of the word "container" itself, nothing more. (Jazz Br. at 9 (citing '650 patent at col. 10, ll. 3–6, col. 16, ll. 2–7).) Yet the utterance of the word "container" alone cannot possibly describe a precise structure in the specification when it does not do so in the claims. This argument is entirely circular, by Jazz's own admission. (*See* Jazz Br. at 9 ("Thus, the 'third container means' can be a container.").) Not to mention that these generic specification disclosures are not clearly linked to any distinct element or its functions, and are therefore legally insufficient. (White Decl. Ex. 6, '650 patent at col. 10, ll. 3–6, col. 16, ll. 2–7.) *Med. Instrumentation & Diagnostics Corp. v. Elekta AB*, 344 F.3d 1205, 1210 (Fed. Cir. 2003).

Jazz next points to an excerpt in the specification about "injection or blow-molded plastic containers," but it is only Jazz, and not the specification itself, that now ties the "third container means" and its recited functions to this structure. (Jazz Br. at 9 (citing '650 patent at col. 16, ll.

29–32).) Indeed, the specification discloses only that these structures can perform the function of retaining *one* distinct container (vials), not each of the first container means, second container means, and delivery vehicle, as the claimed "third container means" must do. (White Decl. Ex. 6, '650 patent at col. 16, ll. 28–31, claim 17.)

Tellingly, Jazz's assertion that these "injection or blow-molded plastic containers" are the corresponding structure in the specification contradicts the fact that Jazz has not, and does not now, propose that the "third container means" be construed to encompass only this structure and equivalents thereof, per § 112, ¶ 6. (Jazz. Br. at 5; D.I. 315, Joint Claim Construction Statement at 11.) 35 U.S.C. § 112, ¶ 6 (A means-plus-function claim term "shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.") Apparently even Jazz does not truly consider this to be the essential specification disclosure that can avoid indefiniteness.

For the reasons stated above and in Defendants' opening submission, the term "third container means" should be held to be an indefinite means-plus-function element as a matter of law.

III. The '506 Patent.

A. "Greater than about 500 mg/mL."

Jazz's position is that even if construction of this term is needed, "about" must mean something. But "about" is not the term to be construed, "greater than about 500 mg/mL" is. And in drafting this claim, the patentees created an ambiguity, namely the meaning of "greater than" "about 500 mg/mL." The specification guides the answer to that question. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996) ("[T]he specification is always highly relevant to the claim construction analysis.") In Table 2, it describes concentrations of compositions providing resistance to microbial growth, and the lowest concentration

demonstrating resistance to microbial growth is 500 mg/mL. (White Decl. Ex. 8, the '506 patent at col. 11, l. 41 – col. 12, l. 12 (Table 2).) A person of ordinary skill, relying on the specification, would understand that the claimed compositions perform as claimed to a lower limit of 500 mg/mL. The specification does not describe lower limits less than 500 mg/mL. To construe "about 500mg/mL" to include levels below 500 mg/mL would contradict the specification itself. Therefore, the Court should adopt Defendants' construction as it is the only one consistent with the specification.

IV. The '306 and '302 Patents.

A. "Administering."

Jazz argues that Defendants have not shown there is only a single definition of "administering" to be applied here, but instead dictionaries such as the one Defendants cited also include alternate definitions of "administering." First, the exemplary definition of "to give out or dispense" that Jazz cites is consistent with the very definition Defendants seek, namely "to give or apply." And as to the alternate definitions of "administering" Jazz cites, these may be rejected because the claim language would not be sensible with these other definitions. For instance, Jazz cites the definition "to manage or supervise execution, use, or conduct." This court recently rejected such a construction of "administering" in an analogous context. *See Sanofi-Aventis U.S. LLC v. Fresenius Kabi USA, LLC*, No. 14-8079, 2016 WL 5898627, at *7 (D.N.J. Oct. 7, 2016). In that case, the plaintiffs sought the construction of "administering" to mean "prescribing, supervising, or managing the formal taking of." (*Id.*) In support of that definition, the plaintiffs cited a dictionary definition of "to manage or supervise the execution, use, or conduct of." (*Id.*) The court rejected that construction, and instead adopted the defendants' construction of "delivering into the body of the patient" to be consistent with the specification. (*Id.* at *7–8).

While Jazz identifies some cases in which "administering" has been construed to mean something other than "to give or apply," those cases actually support Defendants' construction. For example, in *Shire LLC v. Amneal Pharm., LLC*, No. 11-3781, 2013 WL 4045622, at *17 (D.N.J. Aug. 8, 2013), the court declined to limit "administration" to mean "physically delivering into the body of the patient" because "there [was] certainly no basis to conclude that the patentees invented a treatment in which physicians physically delivered the medication into the body of the patient." (*Id.*) Instead, the court agreed that "administering" is performed by the patient, which is consistent with Defendants' position. Similarly, the court in *BMS* did not construe "administering" as merely having its "plain and ordinary meaning"—which is what Jazz advocates for here. *Bristol-Myers Squibb Co. v. Apotex, Inc.*, No. 10-5810 MLC, 2013 WL 1314733, at *10-12 (D.N.J. Mar. 28, 2013). Instead, it relied on extrinsic evidence to articulate a specific construction (albeit, in that case, one advocated by the plaintiff), just as Defendants' urge here. (*Id.*)

Jazz also cites *Iovate Health Scis., Inc. v. Bio-Engineered Supplements & Nutrition, Inc.*, No. 07-46, 2008 WL 2359961, at *3 (E.D. Tex. June 5, 2008) and provides the parenthetical statement: "explaining that 'to mete out' encompasses the entire process of 'delivering into a body, or the management or supervision whereby something is delivered into a body'". This appears to be an error, as the cited discussion concerned the construction of the term "administering/administered," and the term "to mete out" does not appear anywhere in the court's order. In any event, in that case the plaintiff sought a construction limited to managing the administration of something because, unlike in the present case, that was how the specification used the term. (*Id.*) The court nonetheless also included the more natural construction of "delivering into a body" because nowhere did the specification *exclude* that

meaning. (*Id.*) In contrast, the patents here do not repeatedly use the term "administering" to refer to managing the administration of a drug.

In addition to the aforementioned *Sanofi-Aventis* decision of this district court, other recent decisions also show that "administering" should not be given the sort of broad license Jazz requests. The context of medical administration is what confines the meaning of the claim. Where plaintiff sought to construe "administering" as "to mete out," that construction was rejected because "the term would be so overly broad as to cover nearly any action associated with dispensing a drug." *Andrulis Pharm. Corp. v. Celgene Corp.*, 13-1644, 2015 WL 3978578, at *3 (D. Del. June 26, 2015), *aff'd*, No. 2015-1962, 2016 WL 3755929 (Fed. Cir. July 14, 2016). The court continued:

> It would not be appropriate for "administering" in the claim to cover the acts of pharmacists, sales people, or essentially anyone giving or handing the drug to a patient. Instead, administering must be tied to the process of administering the medicine in the context of immediately providing treatment.

(*Id.*) Here too, within the context of the claimed method of treatment, "administering" must cover the act of treatment itself, "to give or apply" the drug, and cannot be permitted to include any conceivable connection to drug administration.

Another court has also helpfully explained that "administering" is limited to the giving or applying of a drug, and does not include the direction of such drug administration. *Takeda Pharm. Co. Ltd. v. Actavis Labs. FL, Inc.*, No.15-451, 2016 WL 3193188, at *3-4 (D. Del. June 6, 2016) (construing "administering" to mean "delivering into the body"). The court reached its decision in part because the plaintiffs did not cite "a single portion of either specification where some form of the word administer refers to the verbal directives or treatment management activities of physicians." (*Id.* at *3.) Tellingly, Jazz has also failed to show that Defendants'

construction is inconsistent with the specification, and failed to provide evidence that justifies a construction broader than that proposed by Defendants.

B. "Also being administered."

Jazz takes the untenable position that the term "also being administered" "does not require construction." (Jazz Br. at 17.) Instead, according to Jazz, this term "should be given its plain-English meaning within the context of the claim in which it appears." (*Id.*) Jazz ignores this term's ambiguities and asks this Court to punt rather than provide clarity now.

Federal Circuit case law is clear that "[a] determination that a claim term 'needs no construction' or has a 'plain and ordinary meaning' may be inadequate when a term has more than one 'ordinary' meaning or when a reliance on a term's 'ordinary meaning' does not resolve the parties' dispute." *O2 Micro Int'l, Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1361 (Fed. Cir. 2008); *Eon Corp. IP Holdings v. Silver Spring Networks*, 815 F.3d 1314, 1318 (Fed. Cir. 2016).[5] Jazz's myopic treatment ignores the real problem—here there is no single "plain-English" meaning of "also being administered" in the '306 patent claims.

For example, standing alone, the term "also being administered" leaves open whether the relevant '306 patent claims require the patient receiving GHB to receive valproate at the exact moment in time that the patient receives GHB; within a time period during which the effects of previously administered valproate are still operative in the patient (*see* Defendants' proposed construction); or within some other temporal framework vis-à-vis the administration of GHB to the patient.

Defendants' proposed construction of "also being administered" resolves this ambiguity

[5] *See also* Proposed Amendment to Rule 4.2 of the District of New Jersey Local Patent Rules, available at http://www.njd.uscourts.gov/sites/njd/files/PatentRules9-16.pdf, providing that the parties' exchange of proposed constructions shall "includ[e] constructions for each term for which 'plain and ordinary' meaning is asserted."

while adhering to this term's plain and ordinary meaning in light of all the intrinsic evidence of the '306 patent. Claims 19, 30, and 33 each are directed toward a method of treatment that requires, among other things, "determining if the patient is also being administered valproate," and recommending reducing (or "a decrease in") the dose of GHB salt. (White Decl. Ex. 10, the '306 patent at col. 25, ll. 38–50 (LUP.GHB 08355); *id.* at col. 26, ll. 25–29 (LUP.GHB 08355); *id.* at col. 26, ll. 42–50 (LUP.GHB 08355).) As Defendants' Opening Brief set forth, the specification and prosecution history of the '306 patent make clear that the purported reason for any reduction in the GHB dose is driven by the effects of valproate in the patient, which is a meaningful consideration only when the effects of the previously administered valproate are still operative in the patient. (Defs. Br. at 21-22.) Defendants' construction recognizes this.[6] (*See, e.g.*, White Decl. Ex. 10, the '306 patent at col. 1, l. 66 – col. 3, l. 52 (LUP.GHB 08343-44) (purporting to provide examples of embodiments of the alleged invention in which the dosage amount of GHB is reduced or decreased in order to safely administer GHB with MCTs, and suggesting that purported safety considerations stem from potential additive effects or potential drug/drug interactions); White Decl. Ex. 11, the '306 patent PH, 11/13/13 Response at 10 (LUP.GHB 009459) (Applicants attempting to distinguish cited prior art references disclosing use of GHB and/or valproate by arguing that if the cited prior art references were combined, the references "would not teach or suggest that there would be a change in the GHB *in vivo* effect caused by valproate").)

By contrast, Jazz ignores whole categories of intrinsic evidence. Jazz purports to consider "the context of the claim in which [this term] appears," (Jazz Br. at 17), but it does not even

[6] Jazz ignores the ambiguity in the term "also being administered" by twisting Defendants' proposed construction to suggest it somehow means that "the term refers to two doses of the same drug being administered to a patient." (Jazz Br. at 17.) Not so. Defendants' argument properly addresses what it means when a patient is "also being administered" valproate.

attempt to reconcile the remainder of the patent or its prosecution history. Case law is clear that the entirety of the intrinsic record should be considered—the claims, the specification, and the prosecution history. *Nystrom*, 424 F.3d at 1144-45 (A party is "not entitled to a claim construction divorced from the context of the written description and prosecution history."); *Eon Corp.*, 815 F.3d at 1320 ("Ordinary meaning is not something that is determined 'in a vacuum.'").

For these reasons, the Court should adopt Defendants' proposed construction of "also being administered": "the administration of a drug to a patient within a time period during which the effects of a previously administered dose of the drug is still operative in the patient."

C. "Currently taking."

Jazz's proposed treatment of "currently taking" fails for similar reasons as its argument regarding "also being administered." Again, Jazz ignores the ambiguities of this term and simply concludes that the term "currently taking" needs no construction.

Jazz's approach is improper. As with "also being administered," the term "currently taking," when read in a vacuum as Jazz does, leaves open whether the patient receiving GHB must "take" valproate at the exact moment in time that the patient is administered GHB; within a time period during which the effects of previously administered valproate are still operative in the patient; or at some other temporal framework vis-à-vis with the administration to the patient of GHB. Jazz's proposal that no construction is necessary improperly fails to resolve this ambiguity. *See O2 Micro*, 521 F.3d at 1361; *Eon Corp.*, 815 F.3d at 1319.

Unlike Jazz, Defendants' proposed construction reflects the plain and ordinary meaning of "currently taking" in view of the totality of the intrinsic evidence. As with the '306 patent claims, in the context of the '302 patent claims and specification, the purported reason for any reduction in the dose of GHB is driven by the effects of divalproex sodium in a patient. And as

with the ’306 patent, the ’302 patent specification states that the alleged invention relates to methods of safely administering GHB with MCTs, including valproate, in view of potential additive effects of or potential drug/drug interactions between GHB and valproate (or other MCTs). (*See, e.g.*, White Decl. Ex. 12, the ’302 patent at col. 1, l. 64 – col. 3, l. 50 (LUP.GHB 013543-44) (purporting to provide examples of embodiments of the alleged invention in which the dosage amount of GHB is reduced or decreased in order to safely administer GHB with MCTs, and suggesting that purported safety considerations stem from potential additive effects or potential drug/drug interactions); *see also id.* at col. 18, ll. 48-53 (LUP.GHB 013551).) Necessarily, any effects of valproate in a patient are present, if at all, only when a patient is “currently taking” valproate such that the valproate is still operative in the patient, (*see, e.g., id.* at col. 8, ll. 37–41 (LUP.GHB 013546).) The prosecution history of the ’302 patent also accords with Defendants’ proposed construction. (*See generally* White Decl. Ex. 13, the ’302 patent PH, 9/15/14 Response at 7-11 (LUP.GHB 014660-64) (Applicants attempting to distinguish cited prior art disclosing the use of valproate and GHB by relying on adjusting amount of GHB upon concurrent administration of divalproex sodium and the effect of such concurrent administration).)

Jazz attempts to argue that by relying on the specification, Defendants somehow “equate the meaning of ‘currently taking’ with the agreed-upon construction of ‘concomitant.’” (Jazz Br. at 19.) Not so. Defendants cite the ’302 patent’s specification’s discussion of the treatment of patients, including its description of “concomitant,” in order to evaluate the full context of “currently taking” within the full intrinsic record. By contrast, Jazz simply parrots the legal standard – that there is a “heavy presumption” that “currently taking” has its “ordinary meaning.” (Jazz Br. at 19 (citing *Elbex Video, Ltd. v. Sensormatic Elecs. Corp.*, 508 F.3d 1366,

1371 (Fed. Cir. 2007).) Yet, Jazz at no point explains what the supposed "ordinary meaning" of "currently taking" is. Jazz's efforts to hide behind the legal standard while providing no meaningful explanation fails.

For these reasons, the Court should adopt Defendants' proposed construction of "currently taking" as "the administration of a drug to a patient within a time period during which the effects of a previously administered dose of the drug is still operative in the patient."

CONCLUSION

For the above reasons, Defendants respectfully request that the Court construe the terms identified herein consistent with Defendants' proposed constructions.

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